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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
MORAN, M	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/942,369	Applicant(s) Chen et al
	Examiner Marjorie Moran	Group Art Unit 1623

☒ Responsive to communication(s) filed on *Feb 11, 1999*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-11 and 19-30* is/are pending in the application.

Of the above, claim(s) *1-11 and 19* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *20-30* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application contains claims 1-11 and 19 drawn to an invention nonelected with traverse in Paper No. 7, filed 10/5/98. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

In view of the new declaration and amendment filed 2/11/99 , objections to the declaration and abstract, and all rejections to claims 12-18 are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 27 recites a method of detecting a majority of pathogens associated with a disease state in lines 1-2, and of simultaneously determining the susceptibility of such pathogens to antimicrobial agents in lines 4-5. In addition, claim 27 recites pathogens associated with a disease state which are not solely coliforms in lines 6-7. Claim 27 also recites a medium capable of sustaining growth of a majority of pathogens in lines 11-12, 19-20, and 29-30. Pathogens associated with a disease state which are not solely coliforms, and a medium capable of sustaining growth of a majority of pathogens are not recited anywhere in the specification or claims as originally filed. In addition, neither a method of detecting a majority of pathogens nor of simultaneously determining the susceptibility of such pathogens to antimicrobial agents is recited in the specification. While the specification teaches by example on p. 28 that "common gram-negative uropathogens" may be detected and their susceptibility to particular antibiotics determined, detection and simultaneous susceptibility determination of a "majority" of urinary pathogens is not exemplified. Likewise, "target organism specific medium" and "uropathogen specific medium" are defined on p. 12 of the specification as media capable of selectively sustaining the growth or viability of target microorganisms or of primary urinary gram negative pathogens, respectively. These are not media capable of sustaining the growth of a "**majority** of pathogens associated with a disease state", as recited in claim 27 (emphasis added by the examiner). Claim 27 also recites "a disease state which may be caused by at least two different

genera of microbes" in lines 3-4. While this phrase is not specifically recited in the specification, the specification does disclose such disease states as urinary tract infections, ear infections, and skin infections. It is commonly known in the art that all of these disease states may be caused by one or more genera of microbes, acting singly or in concert. The disease states disclosed in the specification as originally filed are considered by the examiner to exemplify disease states caused by at least two different genera of microbes, therefore disease states caused by at least two different genera of microbes are not new matter. However, for the reasons set forth above, pathogens associated with a disease state which are not solely coliforms, a medium capable of sustaining growth of a majority of pathogens associated with a disease state, and a method of detecting a majority of pathogens and of simultaneously determining the susceptibility of such pathogens to antimicrobial agents are not taught or exemplified in the specification or claims as originally filed, and are therefore new matter.

Claims 27 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the phrase "A method of detecting in a biological sample the presence of a majority of pathogens associated with a particular disease state" in lines 1-3. It is unclear if applicant intends to actually detect a majority of the pathogens associated with a disease (for which the disclosure is neither supporting nor enabling), or if applicant merely intends a method

capable of detecting a majority of pathogens associated with a particular disease, not necessarily all at once, therefore this claim is indefinite. For purposes of prior art searching, the examiner assumed the latter.

Also regarding claim 27, it is unclear how the phrase "provided that the pathogens ... are not solely coliforms", as recited in lines 6-7, are further limiting of the method. Does applicant intend that his method NOT detect coliforms? Or does applicant intend for his method to be used only when the disease state is one which is not associated with coliforms? Use of this phrase therefore renders the claim indefinite.

Claim 30 recites the limitation "the biological fluid" in line 1. There is insufficient antecedent basis for this limitation in the claim, therefore this claim is indefinite.

In addition, claim 30 recites " a chemical sample" or "an environmental sample" in line 3 Neither of these are biological fluids, as recited in line 1 nor, necessarily, biological samples, as recited in claim 27, from which claim 30 depends. As it is unclear whether the claim is intended to be limited to biological fluids, biological samples, or any sample which may contain microorganisms, this claim is indefinite.

Claim Rejections - 35 USC § 103

Applicant's arguments with respect to claims 12-18 have been considered but are moot in view of the new ground(s) of rejection.

The examiner would like to point out that a medium containing multiple antibiotics, as recited in the arguments on p. 8 of the response filed 2/11/9 is not a limitation recited in any of the claims, nor is a method of detecting the great majority of members of a particular class of microorganisms, as recited on p. 9 of the response, recited in any of the claims. In addition, applicant argues in lines 9-12 on p. 10 of the response that "there is no media available in the art which is capable of selecting for a majority of the organisms responsible for a particular disease state." The examiner disagrees with this statement. The examiner would like to further point out that applicant's disclosure does not give support for such a medium (see above); therefore, if such a medium is not supported by the prior art, then applicant's disclosure is not enabling for such a medium. Applicant argues on p. 11 of the response filed 2/11/99 that BROCCO does not teach a selective growth medium, but on p. 12 states that "the medium of BROCCO selects for" certain bacteria. The examiner interprets any medium which "selects" for or against the growth of particular organisms to be a selective medium. Applicant should note that BROCCO is not cited for teachings of selective media, but for his teachings of particular antibiotics to which microbes, specifically urinary pathogens, may or may not be susceptible.

Claims 20-25 and 27-30 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of SANDERS (B).

Applicant claims a method of simultaneously detecting urinary pathogens in a biological sample and determining susceptibility of the pathogens to antimicrobial agents wherein portions of

a biological sample are separately added to compartments of an assay device which comprise, separately, a medium capable of sustaining growth of total microbial organisms, a uropathogenic specific medium, and an antimicrobial susceptibility interpretation medium, then examining the different compartments to determine presence and susceptibility of the urinary pathogens. In claim 21, applicant limits his biological sample to urine. In claims 22-23, he limits the pathogens to primary gram negative urinary pathogens, specifically Enterobacteriaceae. In claims 24-25, applicant limits his pathogens to specific species.

JOHNSON teaches a process (method) for detecting and determining the susceptibility of specific microorganisms to antibiotics wherein a clinical sample is added to separate wells or a microtiter plate, which wells comprise a selective culture medium or blends of the selective culture medium and known antibiotics, the plate is cultured, then the wells examined for growth of microorganisms (col. 10, line 45-col. 12, line 2 and col. 7, lines 33-36). JOHNSON further teaches that his method and device may be used to analyze urinary pathogens, specifically *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella*, *Enterobacter*, *Proteus* spp., *Enterococcus*, and *Staphylococcus aureaus* (col. 3, lines 31-36). JOHNSON also teaches that his sample may be urine, blood or spinal fluid, and that growth in individual growth wells permits a positive test for indication of organisms (col. 7, lines 39-46). JOHNSON does not specifically teach medium capable of sustaining growth of total microbial organisms.

As previously set forth in the office action of 11/9/98, SANDERS teaches nutrient media capable of sustaining growth of a wide variety of microorganisms (col. 4, lines 12-34) for use in a

method for determining the susceptibility of microorganisms to antibiotics (col. 1, lines 34-38).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the medium of SANDERS in the method of JOHNSON where the motivation would have been to provide a positive control for microorganismal growth, as suggested by JOHNSON. It would further have been obvious to detect multiple pathogens in the method of JOHNSON where the motivation would have been to determine the presence (and susceptibility) of any microorganisms present and contributing to a disease state in order to determine an appropriate course of treatment. No criticality or unexpected result has been shown for detecting more than one organism in the method of JOHNSON. One skilled in the art would reasonably have expected success in incorporating the medium of SANDERS in the method of JOHNSON because JOHNSON teaches sustenance of growth of total microbial organisms, which implies use of a medium. In addition, one skilled in the art would reasonably have expected success in detecting multiple organisms in the method of JOHNSON because JOHNSON teaches that pathogens (plural) can be detected, identified, grouped, and enumerated rapidly (col. 7, lines 34-35) in his method. For these reasons, claims 20-25 and 27-28 are rejected.

Claims 20 and 26 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of SANDERS (B) as applied to claim 20 above, and further in view of BROCCO (E).

Applicant claims a method of simultaneously detecting urinary pathogens in a biological sample and determining susceptibility of the pathogens to antimicrobial agents, as set forth above. Applicant further limits the antimicrobial agents to amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

JOHNSON in view of SANDERS make obvious a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents, as set forth above. JOHNSON in view of SANDERS do not specifically teach amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

As previously set forth in the office action of 11/9/98, BROCCO teaches a method of determining susceptibility of uropathogens, specifically Staphylococcus and Streptococcus, to amoxicillin (p. 5, line 8-p. 6, line 7), and a clavulanic acid mixture (p. 9, line 4-p. 10, line 15).

It would have been obvious to include the amoxicillin and clavulanic acid of BROCCO as antimicrobial agents in the method of JOHNSON in view of SANDERS where the motivation would have been to test susceptibility of microorganisms, specifically urinary pathogens, to any known antibiotics, as suggested by JOHNSON, in order to determine an appropriate course of treatment for a subject infected with the microorganisms. For these reasons, claims 20 and 26 are obvious.

Conclusion

Claims 20-30 are rejected and claims 1-11 and 19 are still withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached at (703) 308-4311. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Marjorie A. Moran
Patent Examiner
Art Unit 1623

mm
4/23/99

KATHLEEN K. FONDA
PRIMARY EXAMINER